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INTERNATIONAL HEALTH GOVERNANCE SYMPOSIUM

The WHO's Institutional and Legal Role in Communicable Disease Epidemics: From Pandemic Influenza to Zika

PEDRO VILLARREAL — 25 April, 2016

Photo by UNMEER/Martine Perret. 15 December 2014

On 1 February, 2016, the World Health Organization´s (WHO) Director-General declared that the Zika virus epidemic in the Americas is a Public Health Emergency of International Concern (PHEIC). The illness caused by this virus is very rarely fatal, and it causes mild symptoms: rash, headaches, conjunctivitis, sometimes fever and joint pains. Besides, an estimated 80% of cases are asymptomatic, which makes it next to impossible to establish an exact number of infected persons. The reason for declaring this event as a PHEIC was not grounded on the severity of the disease in terms of fatalities. Rather, the major source of concern was the then-suspected link between Zika virus and a surge in cases of microcephaly and a danger of developing Guillain-Barré syndrome.

This has been the fourth time this legal figure is employed to address an issue related to the international spread of an infectious disease. Article 12 of the *International Health Regulations (IHR)* of 2005 contemplates the possibility of the WHO's Director-General declaring a PHEIC. As a procedural requirement for doing so, an Emergency Committee

composed of experts needs to be summoned, according to articles 48 & 49 of the *IHR*. Every PHEIC has had its own particular features, both from a medical and an institutional-legal perspective. The declaration of Zika as a PHEIC further shapes the understanding of why and how this figure is employed by WHO officials. It does not adopt a rigid and restrictive approach towards which type of diseases warrant declaring a PHEIC, rather leaving this for case-by-case assessments. Therefore, in order to further grasp the broad nature of this legal figure, a brief overview of each PHEIC so far can be useful for understanding some elements that might be shared, and others that are contrasted between them.

Enter the IHR: The 2009-2010 H1N1 Influenza Pandemic

On 25 April, 2009, the Director-General of the WHO declared, for the first time, that the unusual cases of A(H1N1) influenza reported by Mexico and the United States constituted a PHEIC. Later, on June 11th, 2009, there was also a declaration of the highest pandemic alert level (then level 6), which led to criticisms from other countries that were not as affected by the virus as Mexico and the United States. The main argument was that pharmaceutical companies made huge profits (as they usually do) due to the declaration of a pandemic.

The backlash against the WHO resulted, among other things, in an investigation within the Council of Europe due to what was perceived as undue influence by the pharmaceutical industry. Although the eventual report presented at the Parliamentary Assembly of the Council did not find evidence of malfeasance, it did include criticism related to lackluster transparency in decision-making. Not disclosing the names

of members of the Emergency Committee, which falls under the discretion of the WHO Director-General since there is no explicit legal provision in the *IHR* mandating it, also added fuel to the fire.

After the 2009-2010 influenza pandemic, an extensive report by an IHR Review Committee was issued. It contained, *inter alia*, several recommendations for enhancing decision-making within the WHO. However, there were no calls for a reform of any of the provisions within the *IHR*.

The push against Poliomyelitis

On 5 May, 2014, a PHEIC was declared for the second time, in relation to the spread of wild poliovirus throughout regions of Africa and the Middle East. This was seen as the consequence of both an anti-vaccination sentiment, as well as longstanding military conflict that dramatically undermined the provision of health services throughout these regions.

The wild poliovirus PHEIC declaration can be seen as a companion to the decades-old global polio eradication campaign. This way, it would serve as a catalyst for this goal, and not just as a reaction to a new event.

As the objective of full polio eradication is increasingly closer to being in sight, the justification for using the legal figure of a PHEIC for this purpose constitutes a precedent for expanding its scope. This can make the figure more flexible in order to deal with different types of challenges.

Deadly delay: The Ebola outbreak in West Africa

Despite initial reports in March 2014 by Médécins Sans Frontières about the out-of-control spread of Ebola virus throughout Guinea, a PHEIC was only declared on 8 August of the same year. The WHO was then criticized for the opposite reason than during the H1N1 influenza pandemic: In this case, it was chastised for not raising the alarm fast enough. While this is a difficult argument to make due to the issue of causality, it is believed that had this alarm been raised before, more resources could have been directed earlier for containing the spread of Ebola.

In September 2014 the United Nations Mission for Ebola Emergency Response (UNMEER) was created as an ad hoc organism to aid in the fight against Ebola. This was also seen as a sign of the lack of capacity by the WHO. In turn, the overall performance of UNMEER was itself the object of criticism as well.

The worst of the West African Ebola crisis seems to be over. The WHO Director-General declared the Ebola PHEIC as formally terminated, although the disease was still present in some regions. Proposals by an IHR External Review Committee on how to reform disease outbreaks decision-making within the WHO are scheduled for discussion at the upcoming 69th World Health Assembly in Geneva. Unlike in the aftermath of the 2009 A(H1N1) influenza pandemic, it might actually include modifying certain provisions of the IHR.

Other, more detailed posts about the Ebola crisis in West Africa can be accessed here and here.

The race for knowledge: The Zika emergency of 2016

The most recent use of a PHEIC by the WHO has been in the ongoing Zika epidemic that started ravaging the Americas and the Caribbean, and is spreading beyond. Some believe that, unlike in the case of Ebola, the WHO's regional body for the Americas, the Pan-American Health Organization, has been able to respond more effectively to the emergency. Resources have been deployed in order to conduct research in the most affected countries, which led to producing evidence supporting the link between Zika and microcephaly. Other legal debates are already in motion, such as the limits of women's sexual and reproductive rights in Latin America. Similarly, possible sanitation measures by health authorities aimed at vector (mosquito) control are also the source of disagreements by commentators.

The criterion for assessing the justification for the declaration of a Public Health Emergency of International Concern is different for Zika virus than for previous instances. According to Annex 2 of the IHR, uncertainty can also be used as a legal argument for declaring a PHEIC. As members of this Emergency Committee stated, the Zika PHEIC Declaration was not made based upon what was known at the time, but rather because of what was not known.

With the shadow of the Ebola crisis still looming large over the WHO as an institution, its actions in the recent Zika crisis can also be construed as a reaction to this pressure. One could argue it was too risky for the WHO to wait until sound scientific evidence is available before reacting: Had the WHO neglected to respond to initial reports of the surge in Zika and microcephaly cases, the posterior discovery of this link would have been yet another blow to its institutional reputation.

The legal framing of PHEICs can be construed as granting this leeway. One of the main reasons for the obsolescence of the 1969 version of the *IHR* was its rigid approach towards diseases, which left new and reemerging pathogens out of its purview. Given how uncertainty is a constant factor at stake when making these decisions, it is understandable to adopt this broad approach. Of course, as shown by the backlash in previous PHEIC declarations, this does not mean the WHO has a "blank check". The conundrum is still how to draw a clear line between over- and underreacting. This is *prima facie* a technical-medical assessment, but, in fact, it acquires a legal dimension at the same time.

In sum, a broader vision containing the previous PHEIC declarations provides insights on the WHO's response to the current Zika epidemic. Their similarities and differences can be appraised for grasping how wide this figure can be. Analyzing whether declaring a PHEIC is legally justified requires case-by-case assessments. The complexities of every communicable disease outbreak imply that a definite, "one-size-fits-all" legal category is a longshot.

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